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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,988	07/02/2003	Robert J. Chambers	PC11897B	4364
28523	7590	03/29/2004	EXAMINER	
PFIZER INC. PATENT DEPARTMENT, MS8260-1611 EASTERN POINT ROAD GROTON, CT 06340			DESAI, RITA J	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/613,988	Applicant(s) CHAMBERS ET AL.	
	Examiner Rita J. Desai	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 19-27 is/are pending in the application.
 4a) Of the above claim(s) 19-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: <u>20040323</u> |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Priority

This application claims priority to US 10/062813 and US provisional 60/265,492 filed 1/31/2001.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13 in part, drawn to compounds and pharmaceutical compositions wherein Y is =CR1a, Q1 is phenyl and R5 and R6 together form a ring as given by 1.3.11-1.3.15, Q2 is a biaryl non hetero ring group 1.21, 1.2.3, 1.2.5, 1.2.9, W1 and W2 are both O and g is 1, j is 1 and all other R's are non-hetero ring containing groups classified in class 546, 514 subclass 268.7, 341,342 .
The first appearing sp. in claim 13, or the 3rd compound in the table on page 106 was further elected for search purposes.
- II. Claims 1-13 in part, drawn to compounds and pharmaceuticals wherein Y, Q1, Q2 W1 W2 and Z are other than as given in group I, classified in various classes and subclasses.
- III. Claims 19-27, drawn to method of treating, classified in class 514 and various, subclasses.

If the compounds are found to be allowable then one method of treating from claims 19-27 will be rejoined limited to the scope of the compound claims.

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The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions The compounds have a different core and hence different bonding and properties.

A preliminary search on the core gave numerous iterations indicating that the core is not the applicants contribution over the prior art.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Robert Ronau on 3/23/04 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-13 in part

drawn to compounds and pharmaceutical compositions wherein Y is =CR^{1a}, Q¹ is

phenyl and R⁵ and R⁶ together form a ring as given by 1.3.11-1.3.15, Q² is a biaryl non hetero ring group selected from 1.21, 1.2.3, 1.2.5, 1.2.9, W¹ and W² are both O and g is 1, j is 1 and all other R's are non-hetero ring containing groups classified in class 546, 514 subclass 268.7, 341,342 .

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The first appearing sp in claim 13, or the 3rd compound in the table on page 106 was further elected for search purposes, and based on a fair interpretation of the legal and chemical equivalence the examiner made the above group.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 19-27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

If applicant's traverse on the grounds that the inventions are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants preserve their right to file a divisional on the cancelled non-elected subject matter in due course, without prejudice.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The information disclosure statement filed 7/2/2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

There is no copy of the 1449. The examiner was unable to obtain the 1449 and also the references from the parent application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some Z substituents as given in the examples, does not reasonably provide enablement for all the various Z as defined in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without undue experimentation.

In re Wands, 8 USPQ2d 1400 (1988),

The specification does not give any guidance as to how each of different Z groups derivatives are prepared. In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

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1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case, Applicants are claiming nicotamide derivatives. Applicants have not disclosed any working examples which would demonstrate, or guide, one skilled in the art as to how all the various derivatives with different Z groups were prepared or obtained. The specification must teach how to make the invention. In re Gardner, 166 U.S.P.Q. 138 (1970). In order to practice the claimed invention, one skilled in the art would have speculate how the various groups were obtained or prepared. Therefore, the instant invention is not enabled. The breadth of the claims is so large and the working examples are so few that they are not commensurate to the scope of the claim, and an undue amount of experimentation would be needed to obtain the compounds of the invention.

Applicants should only limit the Z groups to the ones which are enabled.

Double Patenting

Claims 1-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10062811 and 10066503. Although the conflicting claims are not identical, they are not patentably distinct from each other because they generically claim the same group, wherein B1 and B2 are rings or J1 and J2 are also rings. And A or D is drawn to the various overlapping groups.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented, but have been allowed.

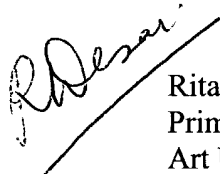
Conclusion

If applicants amend the claims to the elected group and also overcome the 112 rejection the compound claims would be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'R. Desai', is written over a horizontal line.

Rita J. Desai
Primary Examiner
Art Unit 1625

R.D.
March 24, 2004